

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference A31512M	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/010440	International filing date (day/month/year) 19 August 2003 (19.08.2003)	Priority date (day/month/year) 20 August 2002 (20.08.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/202, 9/48, 47/14, 47/02, 47/44, A61P 1/16, 35/00		
Applicant NIKKEN CHEMICALS CO., LTD.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 19 August 2003 (19.08.2003)	Date of completion of this report 24 December 2003 (24.12.2003)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP2003/010440

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-9	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-9	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

2. Citations and explanations

Document 1: EP, 847754, A1 (Leber Co., Ltd.), 17 June, 1998 (17.06.98)
 Document 2: JP, 55-22645, A (Fujisawa Pharmaceutical Co., Ltd.), 18 February, 1980 (18.02.80)
 Document 3: JP, 58-109415, A (Teyasan Pharmaceuticals Co., Ltd.), 29 June, 1983 (29.06.83)
 Document 4: JP, 63-166824, A (Toyo Jozo Co., Ltd.), 11 July, 1988 (11.07.88)
 Document 5: WO, 01-015702, A1 (Chugai Pharmaceutical Co., Ltd.), 8 March, 2001 (08.03.01)
 Document 6: EP, 1046630, A1 (Nikken Chemicals Co., Ltd.), 25 October, 2000 (25.10.00)
 Document 7: JP, 62-77317, A (Kyowa Hakko Kogyo Co., Ltd.), 9 April, 1987 (09.04.87)
 Document 8: JP, 54-46821, A (Grelan Pharmaceutical Co., Ltd.), 13 April, 1979 (13.04.79)
 Document 9: JP, 55-138457, A (Tokai Capsule K.K.), 29 October, 1980 (29.10.80)

[1] The subject matters of claims 1, 7 and 8 do not appear to involve an inventive step in view of documents 1-6 cited in the ISR.

Document 1 describes that, for a preparation containing 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid, the said compound can be made into a pharmaceutical product by a method of manufacturing normal capsules; however, it does not describe that it is injected into a soft capsule containing a light-shielding coat such as the invention of the present application.

On the other hand, injecting compounds unstable to light into soft capsules that are made light-shielded by using a coloring agent such as titanium oxide or yellow ferric oxide to improve their stability in making such compounds into capsulated products, is a well-known, commonly used technique for making preparations (see documents 2-5).

It is within the scope of common technical knowledge that polyprenyl compounds are unstable to light (see document 6, if necessary). So, a person skilled in the art could have conceived of the idea of putting the above-mentioned hexadecapentaenoic acid, which is a polyprenyl compound, in soft capsules containing a light-shielding coat to make such compound into a capsulated preparation without particular creativity. In addition, a person skilled in the art could have conceived of preferable forms of the preparation by exercising normal creativity, as required.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : V.2

[2] The subject matters of claims 2-6 do not appear to involve an inventive step in view of documents 1-8 cited in the ISR.

Refer to the above [1].

Containing various surfactants or vegetable oils dispersed with an active ingredient in preparing soft capsules is a well-known technique (see documents 7 and 8). In addition, a person skilled in the art could have conceived of preferable forms of the preparation by exercising normal creativity, as required.

[3] The subject matter of claim 9 does not appear to involve an inventive step in view of documents 1-9 cited in the ISR.

Refer to the above [1].

Gelatin made into an amber-like state as a coating material in preparing soft capsules is not considered as a particular creation (see document 9).